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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,334	04/07/2000	Jeffrey E. Habben	0803	9587

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/545,334

Applicant(s)

HABBen ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-11,17,20-24,30,32-36,42-48,50-52,54-56,58,59,64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) 9,11,22,24,34,36,48,50-52,54-56,58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,10,17,20,21,23,30,32,33,35,42-47,64 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 4/19/2004 has been entered.

Claims 1-4, 7-11, 17, 20-24, 30, 32-36, 42-48, 50-52, 54-56, 58-59 and 64-65 are pending.

Claims 13-14, 26-27, 38-39, 49, 53 and 60-63 have been canceled.

Claims 9, 11, 22, 24, 34, 36, 48, 50-52, 54-56 and 58-59 have been withdrawn from consideration.

Claims 64 and 65 have been newly added.

Claims 1-4, 7-8, 10, 17, 20-21, 23, 30, 32-33, 35, 42-47 and 64-65 are examined in the present office action.

Rejections and objections not set forth below are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Enablement

Claims 1-4, 7-8, 10, 17, 20-21, 23, 30, 32-33, 35, 42-47 remain rejected and claims 64-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a maize plant transformed with a bacterial isopentenyl transferase encoding polynucleotide (ipt) to produce seeds with increased zeatin levels or expression, increased seed set compared to plants transformed with other genes (page 56, Table 2) and seeds that exhibit vivipary, does not

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reasonably provide enablement for claims drawn to a method of producing a fertile transgenic plant wherein cytokinin content in developing seeds and/or related maternal tissue is increased, a fertile transgenic plant, a method for improving stress tolerance and yield stability, all of which comprise transforming any plant with a genetic construct comprising a tissue-preferred, tissue-specific or temporally-regulated promoter operably linked to a polynucleotide encoding a bacterial isopentenyl transferase. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/17/2003. Applicant's arguments filed 4/19/2004 have been fully considered but they are not persuasive.

Applicants contend that the claimed invention does not, as the Examiner seems to suggest, contemplate isolation of "the gene" encoding the single protein controlling stress tolerance and yield stability. Applicants contend that the specification describes using particular promoters driving expression in developing seeds or related maternal tissue operably linked to a cytokinin modulating enzyme to provide a targeted increase in cytokinin levels leading to improved stress tolerance and yield stability (page 10, 5th paragraph).

The Office contends, given the unpredictability in using any cytokinin modulating enzyme in any plant as stated in the office action dated 3/37/2003, undue trial and error experimentation would be required to practice the claimed invention. In addition, Applicants are arguing limitations not specified in the claims. The claims are drawn to a polynucleotide encoding a bacterial isopentenyl transferase, not to any cytokinin modulating enzyme.

35 USC § 102

Claims 1-2, 4, 17, 30, 42-43, remain rejected and claims 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Houck et al (January, 1993, U.S. Patent Number 5,177,307). This rejection is maintained for the reasons of record set forth in the Official action mailed 12/17/2003. Applicant's arguments filed 4/19/2004 have been fully considered but they are not persuasive.

Applicants contend that anticipation requires that each limitation of a claim must be found in a single reference (page 11, 2nd paragraph). Applicants contend that "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. (MPEP 2112)" (page 11, 7th paragraph). Applicants contend that the theory of inherency requires that a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (page 11, last paragraph). Applicants contend that the Examiner has not provided evidence or reasoning tending to show inherency and Applicants present three prior art references as evidence that products produced by their method do not necessarily possess the characteristics of the claimed product (page 12, 2nd paragraph).

Applicants contend that Roeckel et al teach transforming canola and tobacco with an ipt gene under the control of a developmentally-regulated, a seed-specific promoter. In short, even though ipt was expressed in seeds, the plants displayed altered phenotypes, i.e., reduced roots, more branches. "However, yield was not affected, nor was leaf type, leaf number, days to first flower or days to bolting, in either species" (page 12, 4th paragraph). Applicants contend that Sa et al teach transformed tobacco with ipt operably linked to a promoter that expresses in anthers

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displayed perturbation in the development of anthers and pollen (page 12, 5th paragraph).

Lastly, Applicants contend that “negative effects resulting from directed expression of transgenic IPT were noted in PCT publication WO 00/52169” (page 12, last paragraph).

The Office contends that the Houck et al teach the exact method steps which comprise transforming a plant with the same IPT gene under the control of a promoter that expresses in developing fruits, which are part of “related maternal tissues”, and seeds. Therefore, given that the method steps are the same as Applicants’, given that the constructs are the same as Applicants’, and given that the plant population is the same as Applicants’ claimed invention, it must by necessity have the same outcome. If not, Applicants need to recite additional limitations that result in the desired result which is different from that of the prior art. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method.

35 USC § 103

Claims 1-4, 8, 10, 17, 21, 23, 30, 33, 35, 42-47, remain rejected and claims 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houck et al (January, 1993, U.S. Patent Number 5,177,307) as applied to claims 1-2, 4, 13-14, 17, 26-27, 30, 38-39, 42-43, 49, and 53 above, and further in view of Tomes et al (March, 1999, U.S. Patent Number 5,877,400). This rejection is maintained for the reasons of record set forth in the Official action mailed

12/17/2003. Applicant's arguments filed 4/19/2004 have been fully considered but they are not persuasive.

Applicants contend that they fail to see how the teachings located in column 4, lines 24-27 of the '307 patent establishes a teaching that "increased cytokinins increase the mass of seeds which improves seed set and increases yield" (page 13, 4th paragraph to page 14, 1st paragraph). Applicants contend that another reference to the '307 patent, column 3, lines 1-5, is superficial in disclosing the role of cytokinins in controlling senescence (page 14, 3rd paragraph). Applicants further contend that the term "senescence" suggests the normal decline and death of a plant following reproductive maturity and does not necessarily connote environmental stress, and that "stress" as used in the pending application is directed toward unfavorable conditions affecting a much earlier developmental stage (sentence bridging pages 14 and 15). Lastly, Applicants contend that they fail to find the motivation to combine patents '307 and '400, so as to use the embryo and endosperm expressing promoter of the '400 patent with the teachings of the '307 patent so as to facilitate the method for the modification of cytokinin to increase seed set and seed yield (page 15, last paragraph).

The Office contends that Applicants claims are drawn to a method for producing fertile transgenic plants, a fertile transgenic plant, a method for improving stress tolerance and yield stability and a method for producing plants with increased cytokinin content in developing seeds or related maternal tissue, all of which comprise the same method step which is the introduction of an IPT gene into the plant. The Houck et al reference teaches the exact method step and as such, the theory of inherency anticipates Applicants claims as discussed above. The secondary reference, the '400 patent, teaches other promoters embryo and endosperm expressing promoters

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known in the art prior to Applicants' filing date. Using heterologous promoters to express genes of interest was known and was an accepted practice in the art prior to April, 1999. In regards to "mass of seeds which improves seed set and increases yield", Applicant is arguing limitations not specified in the claims. The Office contends that the "superficial" disclosure of senescence is still a disclosure of senescence and is applicable in regards to the normal decline and death of a plant or the end result of an unfavorable environment.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
June 4, 2004


PHUONG T. BUI
PRIMARY EXAMINER
6/4/04